



Quidel Molecular *C. difficile* Control Set

Positive and Negative

QUIDEL



INTENDED USE

The Quidel Molecular *C. difficile* Control Set is intended to be used as full process controls in molecular testing. This unassayed Control Set for *in vitro* diagnostic use consists of a highly purified, inactivated strain of *C. difficile* (NAP1) and a *C. difficile* free matrix.

INSTRUCTIONS FOR USE

The Quidel Molecular *C. difficile* Controls should be used at the same volume as unknown samples in a validated molecular test methodology. See table below for suggested volumes in specific Quidel Molecular products.

Quidel Molecular Assay	Volume
AmpliVue® <i>C. difficile</i>	Swab Dip*
Solana® <i>C. difficile</i>	Swab Dip*
Lyra® Direct <i>C. difficile</i>	Swab Dip*

*NOTE: Approximately 50 µL

MATERIALS PROVIDED

Cat. #M108

Control Kit (3 vials) – Store at 2°C to 8°C

#	Component	Quantity
CONTROL +	<i>C. difficile</i> Positive Control Part M5040	2 vials/kit 1.0 mL
CONTROL -	Negative Control Part M5031	1 vial/kit 2.0 mL

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Use micropipettes with an aerosol barrier or positive displacement tips for all procedures.
- Avoid microbial and cross contamination of the kit reagents. Follow Good Laboratory Procedures.
- Treat all specimen/samples as potentially infectious. Follow universal precautions when handling samples, this kit, and its contents.
- Proper sample collection, storage, and transport are essential for correct results.¹
- Store assay reagents as indicated on their individual labels.
- Testing should be performed in an area with adequate ventilation.
- Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements.
- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Wash hands thoroughly after handling.

- For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at quidel.com.

STORAGE AND HANDLING OF KIT REAGENTS

Store the kit at 2°C to 8°C until the expiration date listed on the labels.

QUALITY CONTROL

The controls included in the Quidel Molecular C. difficile Control Set are unassayed controls. Control ranges may vary based on testing method. A specific range should be determined for each desired testing method. Each laboratory should establish their own Quality Control ranges and frequency of QC testing based on applicable local laws, regulations and standard good laboratory practice.

LIMITATIONS

- This control has been studied using a molecular testing methodology; it is not intended for use with other methodologies.

CUSTOMER AND TECHNICAL SUPPORT

To place an order or for technical support, please contact a Quidel Representative at 800.874.1517 (in the U.S.) or 858.552.1100 (outside the U.S.), Monday through Friday, from 8:00 a.m. to 5:00 p.m., Eastern Time. Orders may also be placed by fax at 740.592.9820. For e-mail support, contact customerservice@quidel.com or technicalsupport@quidel.com. For services outside the U.S., please contact your local distributor. Additional information about Quidel, our products, and our distributors can be found on our website quidel.com.

REFERENCES

1. CLSI MM13-A: Guidance for the Collection, Transport, Preparation and Storage of Specimens for Molecular Methods 25:31, 2005.

REF

M108 – Quidel Molecular C. difficile Control Set

IVD



EC REP

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PIM108002EN00 (08/17)

GLOSSARY

REF

Catalogue number



CE mark of conformity

EC REP

Authorized representative
in the European Community

LOT

Batch code



Use by



Manufacturer



Temperature limitation



Intended use



Biological risks



Consult e-labeling
instructions for use

CONT

Contents/Contains

IVD

For *in vitro* diagnostic use

CONTROL +

Control positive

CONTROL -

Control negative
